IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:		§	
		§	
	Gad KEREN et al	§	
		§	Confirmation No.: 2139
Serial No.:	09/839,643	§	
		§	
Filed:	April 20, 2001	§	Group Art Unit: 3772
		§	
For:	METHODS AND APPARATUS FOR REDUCING LOCALIZED CIRCULATORY SYSTEM PRESSURE	§	
		§	
		§	Attorney Docket: **34948**
		§	
Examiner:	NGUYEN Camtu Tran	§	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF (37 C.F.R. 41.37)

Sir:

This brief is further to a Notice of Appeal filed on October 6, 2010, and to the Notice of Panel Decision from Pre-Appeal Brief Review dated December 21, 2010.

This Appeal Brief is being filed on or before January 21, 2011, and for which no extension of time fee is due.

REAL PARTY OF INTEREST

The real party in interest of this appeal is the following party: V-Wave Ltd.

RELATED APPEALS AND INTERFERENCES

This appeal has no related proceedings or interferences.

STATUS OF CLAIMS

A. TOTAL NUMBER OF CLAIMS IN THE APPLICATION

The claims in the application are: 1-112.

B. STATUS OF ALL THE CLAIMS IN THE APPLICATION

Claims cancelled: 1-48, 51-58, 60-67, 71-72, 74-77, 79-83, 85, 90-91, 93-96, 104-106, 109-112.

Claims withdrawn from consideration but not cancelled: NONE.

Claims pending: 49, 50, 59, 68-70, 73, 78, 84, 86-89, 92, 97-103, 107 and 108

Claims allowed: NONE

Claims rejected: 49, 50, 59, 68-70, 73, 78, 84, 86-89, 92, 97-103, 107 and 108

Claims objected to: 49

C. CLAIMS ON APPEAL

The claims on appeal are: 49, 50, 59, 68-70, 73, 78, 84, 86-89, 92, 97-103, 107 and 108

STATUS OF AMENDMENTS

An Amendment after a Non-Final Rejection of September 1, 2010 was not filed. Therefore, claims 49, 50, 59, 68-70, 73, 78, 84, 86-89, 92, 97-103, 107 and 108 on appeal herein are as amended in the Response to Office Action filed on April 27, 2010.

SUMMARY OF CLAIMED SUBJECT MATTER

The appealed independent claims in the Application are claims 49, 59, 84 and 103, which are repeated below with reference to passages in the published application providing support, in bold letters.

Independent **claim 49** defines a method of decreasing blood pressure in a heart chamber, comprising:

implanting a shunt between a left atrium and a right atrium of the heart **[paragraph 0038]**, such that a first end of said shunt resides in said left atrium and a second end of said shunt resides in said right atrium **[paragraph 0038, Fig 5]**, thereby enabling blood flow between said left atrium and said right atrium **[paragraph 0018]** and allowing an amount of blood suitable to reduce blood pressure in said left atrium, to flow from said left atrium to said right atrium via said shunt when a pressure differential between said left atrium and said right atrium reaches a threshold **[paragraphs 0012, 0022, 0031-0033]** thereby decreasing blood pressure in a heart chamber.

Independent **claim 59** defines a device for decreasing blood pressure in a heart chamber, comprising:

a shunt configured for positioning within a septum between a left atrium and a right atrium of the heart **[paragraph 0038]** such that a first end of said shunt resides in said left atrium and a second end of said shunt resides in said right atrium **[paragraph 0038, Fig 5]**, said shunt including a valve **[paragraph 0012, 0019]** being configured for opening when a pressure differential between said left atrium and said right atrium is 12 mmHg or above **[paragraph 006]**.

Independent **claim 84** defines a method of controlled decreasing of blood pressure in a heart chamber, comprising:

implanting a valve in a heart septum between two heart atria **[paragraph 0019]**, such that said valve opens responsive to a pressure level of an exacerbated state of heart failure but not under normal pressures of systole and diastole of a normal heart **[paragraph 0022]**.

Independent **claim 103** defines a device for installation in a heart, comprising:

a shunt configured for positioning within a septum between atria of the heart **[paragraph 0038]**; a sensor adapted to sense a parameter indicative of a state of the heart **[paragraph 0026]**; and a controller adapted to control flow through said shunt in response to readings from the sensor **[paragraph 0026]** indicating a pressure above 12mmHg.

Dependent claims **50, 68-70, 73, 78, 86-89, 92, 97-102, 107 and 108** are separately argued by Appellant and are repeated below with reference to passages in the Published Application providing support, in bold letters.

Dependent **claim 50** defines the method of claim 49, wherein

said implanting is effected by positioning said shunt through a septum of the heart and anchoring said shunt using fixation elements attached thereto **[paragraph 0037]**.

Dependent **claim 68** defines the device of claim 59, wherein

said shunt has a diameter of less than 5 mm **[paragraph 0018]**.

Dependent **claim 69** defines the device of claim 59, wherein

said valve is configured to allow passage of a relatively small volume of blood relative to an ejection volume of the heart **[paragraph 0012]**.

Dependent **claim 70** defines the device of claim 59, wherein

said shunt has a length not substantially greater than a thickness of said septum **[paragraph 0018]**.

Dependent **claim 73** defines the device of claim 59, wherein

said valve is capable of gradual opening and/or closing **[paragraph 0022]**.

Dependent **claim 78** defines the device of claim 59, further comprising:

fixation elements attached to opposite sides of said shunt and being for flanking said septum **[paragraph 0017]**.

Dependent **claim 86** defines the method of claim 84, wherein
implanting said valve in the heart comprises implanting between a left atrium and a right atrium, such that opening said valve allows flow of blood from the left atrium to the right atrium **[paragraph 0025]**.

Dependent **claim 87** defines the method of claim 84, wherein
said valve is configured to open only when the pressure in the left atrium is above a predetermined threshold **[paragraph 0022]**.

Dependent **claim 88** defines the method of claim 87, wherein
wherein said valve is configured to open only when the pressure in the left atrium is above 12mmHg **[paragraph 0024]**.

Dependent **claim 89** defines the method of claim 84, wherein
implanting said valve comprises implanting in a manner which leads blood to a right atria of said heart **[paragraph 0025]**.

Dependent **claim 92** defines the method of claim 84, wherein
said valve allows passage of blood therethrough only during diastole **[paragraph 0022]**.

Dependent **claim 97** defines the method of claim 84, wherein
said valve includes a sensor for sensing a state of the heart and wherein said valve opens at least partially responsive to readings of said sensor **[paragraph 0026]**.

Dependent **claim 98** defines the method of claim 84, wherein
said valve is configured to open when the heart suffers from an exacerbated absolute arterial pressure or an exacerbated differential arterial pressure **[paragraph 0022]**.

Dependent **claim 99** defines the method of claim 84, wherein
said valve is configured to close after drainage of an amount of blood sufficient to reduce the mean left atrium pressure by 5mmHg **[paragraph 0033]**.

Dependent **claim 100** defines the method of claim 84, wherein

said valve is configured to open in response to a differential pressure level between its opposite ends **[paragraph 0035]**.

Dependent **claim 101** defines the method of claim 84, wherein said valve is implanted via a percutaneous procedure **[paragraph 0038]**.

Dependent **claim 102** defines the method of claim 84, wherein said valve is implanted in a transseptal hole **[paragraph 0037]**.

Dependent **claim 107** defines the device of claim 103, wherein said controller opens the said valve when said sensor indicates a pressure above 15mmHg **[paragraph 0034]**.

Dependent **claim 108** defines the device of claim 103, wherein said controller opens said valve when said sensor indicates a pressure above 20mmHg **[paragraph 0035]**.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. GROUND OF REJECTION 1 (CLAIMS 49-50, 59, 69-70, 73, 78, 84, 86-89, 92, 97-102-103, and 107-108).

Claims 49-50, 59, 69-70, 73, 78, 84, 86-89, 92, 97-103, and 107-108 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolf et al. (U.S. Patent Application Publication No. US 2002/0165606 AI).

B. GROUND OF REJECTION 2 (CLAIM 68)

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. (U.S. Patent Application Publication No. US 2002/0165606 AI), presented above, and further in view of Wilk (U.S. Patent No. 7,294,115).

ARGUMENTS

A. GROUND OF REJECTION 1 (WOLF ET AL.)

Claims 49-50, 59, 69-70, 73, 78, 84, 86-89, 92, 97-102-103, and 107-108 stand rejected under 35 U.S.C. §102(e).

In rejecting the claims of the present application, the Examiner stated the following in the Office Action:

"Wolf et al discloses in Figures 2-4 & 7 a differential pressure regulating device comprising a shunt (12, 34) positioned in heart wall between two heart chambers or vessels to enable blood/fluids to flow therebetween (paragraph 0028), and an adjustable valve device (10) to regulate the blood/fluids."

[Office Action, dated September 1, 2010, page 3]

While Wolf et al. describe shunts for facilitating blood flow, such shunts and related methods are designed for routing blood from a heart chamber to an artery for the sole purpose of providing oxygenated blood to ischemic tissues (paragraph 0035 of Wolf et al.). As is clearly shown in Figure 7, the conduit of Wolf et al. shown in Figures 2-4 is positioned with the inflow at the left ventricle (designated *LV* in Figure 7) and the outflow at a coronary artery (designated *CA* in Figure 7).

Wolf et al. refers to heart chambers since these tissue structures are traversed on route to the heart wall, and serve as a source for shunting blood into a coronary artery as is clearly described in paragraphs 0038 and 0040-0041 (emphasis added):

"The conduit may be introduced into the heart wall in a variety of ways, including by a catheter threaded through the femoral artery into the aorta and thence into the left ventricle and, if necessary, the left atrium; or by a catheter threaded through the femoral vein into the inferior vena cava and thence into the right atrium and right ventricle. Alternatively, the conduit may be introduced through a surgical incision in chest wall (thoracotomy) or sternum (sternotomy)."

"The opening through the heart wall (including endocardium, myocardium, and epicardium) and coronary artery can be formed in a variety of ways, including by knife or scalpel, electrocautery, cryoablation, radiofrequency ablation, ultrasonic ablation, and the like. Other methods will be apparent to those of ordinary skill in the art."

"Referring now to FIGS. 1A and 1B, a coronary artery bypass is accomplished by disposing a conduit 12 (FIG. 1B) in a heart wall or myocardium MYO of a patient's heart PH (FIG. 1A). The conduit 12 preferably extends from the left ventricle

LV of heart PH to a clogged coronary artery CA at a point downstream of a blockage BL to create a passageway 8 therethrough."

In sharp contrast, the present invention is specifically designed for decreasing pressure in the pulmonary circulation and left atrium by routing blood from the left atrium to the right atrium via a shunt which is positioned through the septum with one open end in the left atrium and the other in the right atrium. Such a shunt configuration is neither taught nor suggested by Wolf et al. and would not achieve the clinical results sought thereby.

Increased pressure in the left atrium secondary to CHF causes congestion of the pulmonary vasculature and leads to pulmonary edema which is characterized by respiratory stress, and specifically dyspnea (shortness of breath) on exertion and in severe cases, at rest.

CHF patients suffering from pulmonary edema are typically treated with ACE inhibitors in order to try and counteract the deleterious effects of cardiac remodeling and to minimize pulmonary symptoms (dyspnea).

The present invention provides an alternative to such drug treatment. By enabling blood flow from the left atrium to the right atrium when the left atrial pressure exceeds that of the right atrium, the present invention reduces left atrial pressure and as a result reduces pulmonary edema and related symptoms.

A.1 REJECTION OF INDEPENDENT CLAIM 49

With respect to Independent claim 49, the Examiner stated the following in the Office Action:

"Regarding claim 49 requiring the shunt between a left atrium & a right atrium of the heart, Wolf et al reference discloses the "chambers" are referred to the left & the right chambers (paragraph 0028 line 1-3) and the "heart wall" is referred to interatrial septum (paragraph 0029), which is between the left atrium & the right atrium, as such, the Wolf et al's shunt (12, 34) meets the limitations in claim 49."

[Office Action, dated September 1, 2010, page 3]

The Examiner further states that *the Wolf et al shunt (12, 34) would perform the method of decreasing blood pressure in a heart chamber.* [Office Action, dated September 1, 2010, page 4]

Appellant would like to point out that the question whether the shunt would or would not be capable of shunting blood from a left atrium to a right atrium is immaterial to the rejection of method claim 49.

Claim 49 describes a method of reducing pressure in a heart chamber which is effected by implanting a shunt in a septum separating the left and right atria. The implantation approach and the shunt are specifically designed for enabling:

"blood flow between said left atrium and said right atrium and allowing an amount of blood suitable to reduce blood pressure in said left atrium, to flow from said left atrium to said right atrium via said shunt when a pressure differential between said left atrium and said right atrium reaches a threshold thereby decreasing blood pressure in a heart chamber" (claim 49).

In his rejection, the Examiner refers to paragraph [0028] as evidence to positioning of the valved-shunt of Wolf et al. (shown in Figures 2, 4 and 7) between two heart chambers for the purpose of reducing left atrial pressure. Paragraph [0028] of Wolf et al. recites the following:

"As used herein, the term "heart chamber" primarily refers to the interior, or lumenal, aspect of the left or right ventricle or the left or right atrium. The term "conduit," "stent," and "tube" herein refer to physical structures, preferably primarily artificial, that can be positioned between two or more chambers or vessels, to allow blood flow from one chamber or vessel to another. A "shunt" is any natural or artificial passage between natural channels, such as heart chambers or blood vessels. The conduit in the preferred arrangement can be made of a variety of materials, including various metals, such as nitinol, or plastics."

In referring to chambers and vessels, Wolf et al. generally describe the tissue through which conduits can be positioned and does not specifically teach inter-atrial conduits with one end open to the left atrium and the other to the right atrium. The preceding paragraph [0027] of Wolf et al. which describes the problem to be solved provides context to paragraph [0028]:

"As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood that has returned from the lungs to the heart then flows from the heart to the aorta. Some

blood in the aorta flows into the coronary arteries, and the remainder of blood in the aorta flows on to the remainder of the body. The coronary arteries are the primary blood supply to the heart muscle and are thus critical to life. In some individuals, atherosclerotic plaque, aggregated platelets, and/or thrombi build up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. The presence of coronary vasospasm, also known as "variant angina" or "Prinzmetal's angina," compounds this problem in many patients."

Clearly, Wolf et al. do not mention or in fact suggest treatment of pathologies that arise from exacerbated left atrial pressures (e.g. pulmonary edema) or the heart condition leading to such pathologies (CHF) and as such, the suggestion made by the Examiner that Wolf et al. teaches the method of claim 49 is inexplicable.

According to Wolf et al. blockages in coronary arteries can be more effectively corrected/treated using chamber-to-vessel conduit schemes which can be direct (from left ventricle to coronary artery) or indirect (in which cases the conduit can traverse tissues such as the septum), as is clearly described in section [0031] of Wolf et al. (emphasis added):

"In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other nonmyocardial and even noncardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, ***septum****, etc.* "

Regardless of the conduit-routing scheme, Wolf et al. teach that one end of the

shunt is always positioned within a vessel (artery) since the sole purpose of the invention of Wolf et al. is to shunt blood from a heart chamber to a coronary artery.

Any mention of atria or septum is with respect to a source chamber or a tissue through which the conduit passes on route to the artery.

This clearly evident from claims 1, 4 and 5 of Wolf et al. which state (emphasis added):

"1. A coronary bypass conduit comprising: a hollow tube having an interior and an exterior and adapted to be positioned in a wall of a heart between a coronary artery and a heart chamber; and an artificial one-way valve positioned within the interior of said tube.

4. The conduit of claim 1, wherein said heart chamber is a left atrium.

5. The conduit of claim 1, wherein said heart chamber is a right atrium."

Paragraph [0056] of Wolf clearly describes the object of the invention and its advantages over the prior art: *"The present vascular conduit and valve system provides significant improvements in the present treatment of blockages and significant stenoses in the coronary artery".*

Thus, contrary to the Examiners interpretation of Wolf et al., a method of shunting blood from the left atrium to the right atrium for the purpose of reducing left atrial pressure is neither an object of, nor is it described or suggested by, Wolf et al.

A.2 REJECTION OF INDEPENDENT CLAIM 59

With respect to Independent claim 59, the Examiner stated the following in the Office Action:

"Specifically regarding the recitation the valve being configured to open when a pressure differential between said left atrium & said right atrium is 12 mmHg or above, applicant's specification discloses that during diastole, pressure in the left atrium normal is no more than 12 mmHg (page 5 lines 16-18), hence, such disclosure is consistent with Wolfs operation. Namely, the valve would open during when pressure differential is relatively high, more than normal 12 mmHg."

[Office Action, dated September 1, 2010, page 5]

Appellants respectfully disagree with the Examiner's interpretation of the prior art. Wolf et al. do not teach shunts/valves sensitive to pressure differentials of 12

mmHg or more and thus do not teach all the elements of the claimed invention. Notwithstanding, Appellant would like to reiterate that shunts/valves sensitive to this specific pressure differential threshold were designed specifically for the pathology treated by the present invention. Since the conduits of Wolf et al. are designed for shunting blood into a coronary vessel, valves employed thereby would not be designed for selectively allowing forward blood flow above a certain pressure differential, but rather to prevent backflow, as is reiterated throughout the specification of Wolf et al. Furthermore, although maximal systolic pressures are known, such pressures buildup during systole. Since the valve of Wolf et al. is not designed as having a threshold activation pressure, it would open prior to maximal systolic pressure (i.e. well below 12 mmHg).

A.3 REJECTION OF INDEPENDENT CLAIM 84

With respect to Independent claim 84, the Examiner stated the following in the Office Action:

"Regarding claim 84, it is noted that this claim does not define what pressure level is during an exacerbated state of heart failure. In response to the limitations in claim 84, the Wolfs valve (32) closes under normal pressures of systole & diastole of cardiac cycles, as the heart chambers/atria demonstrate no pressure differential therebetween. On the contrary, the Wolfs valve (32) would open in response to a pressure build-up between the heart chambers/atria, a condition of exacerbated heart failure state. As such, the Wolf reference would decrease blood pressure in a heart atria by implanting the valve (32) between the heart atria such that it response to the pressure differential therebetween"

[Office Action, dated September 1, 2010, pages 5-6]

The differences between the present methodology and the teachings of Wolf et al. are outline above with respect to the rejection of method claim 49.

Claim 84 describes a method of controlled decrease of blood pressure in a heart chamber. As is argued hereinabove, Wolf et al. do not describe or suggest such methodology or the need to implant a valve in a heart septum between two heart atria.

Furthermore, Wolf et al. do not describe use of their conduit in heart failure or a valve that "opens responsive to a pressure level of an exacerbated state of heart failure". As such, Appellant fails to understand how the teachings of Wolf et al. are relevant to the method of claim 84.

A.4 REJECTION OF INDEPENDENT CLAIM 103

With respect to Independent claim 103, the Examiner stated the following in the Office Action:

"Regarding claim 103, Wolf et al shunt (12), presented above, discloses shunt (12) is configured for positioning within a septum between atria of the heart (paragraph 0028-0030), a sensor (30) senses the electrical signals produced in the heart muscle, an actuator (36) to control the shunt. Regarding claim 103 reciting the sensor indicating a pressure above 12 mmHg, of which pressure is associated with the systole of cardiac cycle, such pressure has been broadly interpreted as high pressure or exacerbated heart failure pressure. With this interpretation in mind, the Wolf actuator (36) is adapted to control flow through the valve (32) of shunt (12) in response to systole of cardiac cycle (paragraph 0050)"

[Office Action, dated September 1, 2010, page 7]

Claim 103 describes a device for installation in a heart which includes a shunt configured for positioning within a septum between atria of the heart, a sensor and a controller for controlling flow through the shunt in response to readings from the sensor indicating a pressure above 12 mmHg.

As is argued hereinabove, Wolf et al. do not describe use of their conduit in heart failure or a valve that opens responsive to a pressure level of 12 mmHg or above. Appellant would like to point out that Wolf et al. do not teach shunts/valves activatable at pressure differentials of 12 mmHg or more and thus do not teach all the elements of the claimed invention. The Examiner states that "*With this interpretation in mind, the Wolf actuator (36) is adapted to control flow through the valve (32) of shunt (12) in response to systole of cardiac cycle (paragraph 0050)"* implying that the device of Wolf et al. can be adapted for use as the device of claim 103. Such adaptation requires that the sensor and valve be modified to be responsive to the specific pressure threshold claimed, however, nothing in the teachings of Wolf et al. suggest such adaptation.

A.5 REJECTION OF DEPENDENT CLAIMS 50, 69-70, 73, 78, 86-89, 92, 97-102 and 107-108

As is argued hereinabove, Appellant strongly believes that independent claims 49, 59, 84 and 103 are patentable over the prior art cited by the Examiner. As such, any claims directly or indirectly depending from claims 49, 59, 84 and 103 are also patentable over the prior art cited.

B. GROUND OF REJECTION 2 (WOLF ET AL. IN VIEW OF WILK)

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. (U.S. Patent Application Publication No. US 2002/0165606 AI), presented above, and further in view of Wilk (U.S. Patent No. 7,294,115).

In rejecting claim 68 of the present application, the Examiner stated the following in the Office Action:

"*Wolf et al discloses in Figures 2-4 & 7 a differential pressure regulating device comprising a shunt (12, 34) comprising all of the elements as recited in these claims including the shunt (12, 34) is positioned within a septum between a left atrium & a right atrium of the heart, except Wolf does not explicitly disclose the diameter of the shunt (12) is less than 5mm. Wilk discloses in Figures 1-5 shunts with valves to be in the heart wall (HW) from ventricle (LV) into coronary artery (CA), however, Wilk discloses that these shuts with valves may also be applied to the right and left atria (column II lines 64-67). Another embodiment of the shunt Figure 29 discloses shunt (312) having a diameter of 2.0 mm (column 27 lines 16-21), less than 5 mm, thereby, meeting claim 68. Therefore, it would have been obvious to one skilled in the art to construct the Wolfs shunt (12) in the size taught by Wilk, as such would be comfortable to the patient when implanted.*"

[Office Action, dated September 1, 2010, page 7]

As is argued hereinabove, Appellant believes that the device of claim 59 is patentable. Since Wilk does not add information with respect to the specific features of the device which distinguish it from Wolf et al. Appellant is of the opinion that claim 68 is patentable over Wolf et al. in view of Wilk.

CONCLUSION

In the present case, not all of the claimed features have been properly considered and the prior art fails to teach the claimed invention to a person of ordinary skill in the art. The Office Action of September 1, 2010 failed to provide a case in support of the rejections of the claims at least due to the following reasons:

1. The conduits and methodology of Wolf et al. are designed for creating chamber-to-vessel bypasses;

2. Wolf et al. do not teach or suggest pathologies that would benefit from left atrium-to-right atrium shunting of blood; and

3. The present inventors were the first to describe an inter-atrial shunt and use thereof in treatment of elevated left atrial pressures and related pathologies.

Claims 49, 50, 59, 68-70, 73, 78, 84, 86-89, 92, 97-103, 107 and 108 are patentable over the prior art for at least all of the above reasons. Therefore, it is respectfully requested that the Board reverse the Examiner's Rejection of these claims.

Respectfully submitted,

/Jason H. Rosenblum/

Jason H. Rosenblum
Registration No. 56,437
Telephone: 718.246.8482

Date: January 19, 2011

CLAIMS APPENDIX

The text of the claims on appeal is as follows:

49. A method of decreasing blood pressure in a heart chamber, comprising: implanting a shunt between a left atrium and a right atrium of the heart, such that a first end of said shunt resides in said left atrium and a second end of said shunt resides in said right atrium, thereby enabling blood flow between said left atrium and said right atrium and allowing an amount of blood suitable to reduce blood pressure in said left atrium, to flow from said left atrium to said right atrium via said shunt when a pressure differential between said left atrium and said right atrium reaches a threshold thereby decreasing blood pressure in a heart chamber.

50. The method of' claim 49, wherein said implanting is effected by positioning said shunt through a septum of the heart and anchoring said shunt using fixation elements attached thereto.

59. A device for decreasing blood pressure in a heart chamber, comprising:

a shunt configured for positioning within a septum between a left atrium and a right atrium of the heart such that a first end of said shunt resides in said left atrium and a second end of said shunt resides in said right atrium, said shunt including a valve being configured for opening when a pressure differential between said left atrium and said right atrium is 12 mmHg or above.

68. The device of claim 59, wherein said shunt has a diameter of less than 5 mm.

69. The device of claim 59, wherein said valve is configured to allow passage of a relatively small volume of blood relative to an ejection volume of the heart.

70. The device of claim 59, wherein said shunt has a length not substantially greater than a thickness of said septum.

73. The device of claim 59, wherein said valve is capable of gradual opening and/or closing.

78. The device of claim 59, further comprising fixation elements attached to opposite sides of said shunt and being for flanking said septum.

84. A method of controlled decreasing of blood pressure in a heart chamber, comprising:

implanting a valve in a heart septum between two heart atria, such that said valve opens responsive to a pressure level of an exacerbated state of heart failure but not under normal pressures of systole and diastole of a normal heart.

86. The method of claim 84, wherein implanting said valve in the heart comprises implanting between a left atrium and a right atrium, such that opening said valve allows flow of blood from the left atrium to the right atrium.

87. The method of claim 84, wherein said valve is configured to open only when the pressure in the left atrium is above a predetermined threshold.

88. The method of claim 87, wherein said valve is configured to open only when the pressure in the left atrium is above 12mmHg.

89. The method of claim 84, wherein implanting said valve comprises implanting in a manner which leads blood to a right atria of said heart.

92. A method according to claim 84, wherein said valve allows passage of blood therethrough only during diastole.

97. A method according to claim 84, wherein said valve includes a sensor for sensing a state of the heart and wherein said valve opens at least partially responsive to readings of said sensor.

98. A method according to claim 84, wherein said valve is configured to open when the heart suffers from an exacerbated absolute arterial pressure or an exacerbated differential arterial pressure.

99. A method according to claim 84, wherein said valve is configured to close after drainage of an amount of blood sufficient to reduce the mean left atrium pressure by 5mmHg.

100. A method according to claim 84, wherein said valve is configured to open in response to a differential pressure level between its opposite ends.

101. The method of claim 84, wherein said valve is implanted via a percutaneous procedure.

102. The method of' claim 84, wherein said valve is implanted in a transseptal hole.

103. A device for installation in a heart, comprising:

a shunt configured for positioning within a septum between atria of the heart;

a sensor adapted to sense a parameter indicative of a state of the heart; and

a controller adapted to control flow through said shunt in response to readings from the sensor indicating a pressure above 12mmHg.

107. The device of claim 103, wherein said controller opens the said valve when said sensor indicates a pressure above 15mmHg.

108. The device of claim 103, wherein said controller opens said valve when said sensor indicates a pressure above 20mmHg.

EVIDENCE APPENDIX

This appeal has no evidence appendices.

RELATED PROCEEDINGS APPENDIX

This appeal has no related proceedings.